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| EXAMINER | |
|---|---|
| ROYDS, LESLIE A | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1614 | |

DATE MAILED: 09/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/620,221 | KOPPEL, GARY A. | |
| | Examiner | Art Unit | |
| | Leslie A. Royds | 1614 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) 1-17 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-17 are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

**Claims 1-17 are presented for examination.**

***Requirement for Election/Restrictions***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claim 1, drawn to a method for treating behavioral disorders in a patient in need of such treatment comprising the administration of clavulanic acid, classified in class 514, subclass 210.06, for example, for clavulanic acid *per se*.

II. Claims 2-6, drawn to a method of enhancing cognitive function in a patient suffering from a condition characterized by impaired cognitive function comprising the administration of clavulanic acid, classified in class 514, subclass 210.06, for example, for clavulanic acid *per se*.

III. Claims 7-9, drawn to a method for treating a human patient afflicted with a condition, or having a medical history predictive of the development of a condition characterized at least in part by abnormal extracellular glutamate concentration in the brain or nervous tissue comprising the administration of clavulanic acid, classified in class 514, subclass 210.06, for example, for clavulanic acid *per se*.

IV. Claim 10, drawn to a method for treating prostate cancer or benign prostatic hyperplasia comprising the administration of clavulanic acid, classified in class 514, subclass 210.06, for example, for clavulanic acid *per se*.

V. Claims 12-16, drawn to a pharmaceutical formulation comprising clavulanic acid, pharmaceutically acceptable salts or active ester forms thereof that are hydrolyzed

in vivo to clavulanic acid, classified in class 514, subclass 210.06, for example, for clavulanic acid *per se*.

Claim 11 links Inventions I and II and claim 17 links Inventions III and IV. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claims 11 or 17. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. Please reference *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP §804.01.

The inventions are distinct, each from the other because of the following reasons:

Inventions I through IV are patentably distinct. Inventions are patentably distinct if it can be shown that they have different modes of operation, different functions, or different effects and different resultant endpoints (See MPEP § 806.04, MPEP § 808.01). In the instant case, it is noted that the ultimate therapeutic objective of, for example, Invention II (i.e., treating dementia, amnesia or Alzheimer's disease) is distinct from the therapeutic objective of, for example, Invention III (i.e., treating ischemia, epilepsy, etc.), of which each is distinct from the objectives of any one of Inventions IV (i.e., treating prostate diseases) or I (i.e., treating behavioral

disorders).

Inventions I through IV are held to be patentably distinct because the treatment of any one of Inventions I through IV would not necessarily result in the treatment of the other invention. The patient populations in which each method would be practiced are distinctly different (e.g., patients suffering from prostate disease, such as prostate cancer or benign prostatic hyperplasia, and patients suffering from dementia), such that the treatment of one patient population would not necessarily suggest, anticipate or render obvious the treatment of the other patient population. While there may be incidental overlap in the groups of patients experiencing, for example, dementia, and those experiencing, for example, prostate cancer, the endpoints and steps required to treat such conditions are vastly different and do not reasonably suggest, anticipate or render obvious the treatment of the other.

Furthermore, the dosage amounts or frequency and route of administration necessary to effect the treatment of patients with, for example, dementia, would necessarily be independent and distinct from that required for the treatment of patients with, for example, prostate cancer, due to the differences in etiology of such a condition and the activity of the claimed agent(s) in treating such a condition. Moreover, one skilled in the art could practice the invention of any one of Inventions I through IV without practicing the invention of any one of the other inventions. Thus, Inventions I through IV are properly considered patentably distinct from one another.

Inventions V and I-IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product

as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the presently claimed product (i.e., a composition comprising clavulanic acid) can be used in materially different processes of use, namely the treatment of prostate cancer or the treatment of Alzheimer's disease, for example.

Because these inventions are independent or distinct for the reasons given above, they require a different field of search (see MPEP § 808.02) and they have acquired a separate status in the art because of their recognized divergent subject matter, the requirement for election for examination purposes as indicated is proper.

**ELECTION OF INVENTION I REQUIRES THE FOLLOWING ELECTION OF SPECIES:**

Applicant is required under 35 U.S.C. 121 to elect a **single** disclosed behavioral condition as disclosed in the present specification (see, e.g., page 3, lines 9-18) for prosecution on the merits to which the claims shall be restricted in no generic claim is finally held to be allowable. Currently, claim 1 is generic to a plurality of species.

The species of conditions are independent or distinct because each are distinct from one another in etiology, pathophysiological manifestations, treatment protocol (i.e., duration of treatment, dosage amounts of pharmaceutical agents to be administered, frequency of treatment, etc.) and patient population such that a comprehensive search of the patent and non-patent literature for any one such disorder or condition would not necessarily result in a comprehensive search of any one or more of the other disorders or conditions recited in the present claims. Notwithstanding that Applicant may have established an underlying commonality to this genus

of disorders or conditions, namely that each is associated with abnormal extracellular glutamate concentration in the brain or other nervous tissue, it remains that the art does not necessarily recognize such a shared characteristic as being common to each of the disparate disorders encompassed by the claim. For these reasons, they are, therefore, considered patentably distinct. It is noted that the discovery of the treatment of any one of the presently claimed disorders or conditions using the clavulanic acid presently claimed would not necessarily anticipate, reasonably suggest or render obvious the treatment of any one or more of the other disorders or conditions of the present claims for the same reasons described *supra.*

Applicant is reminded that the election of a behavioral disorder that lacks adequate basis in the present specification will raise an issue under the written description requirement of the first paragraph of 35 U.S.C. 112.

**ELECTION OF INVENTION III REQUIRES THE FOLLOWING ELECTION OF SPECIES:**

Applicant is required under 35 U.S.C. 121 to elect a **single** disclosed condition as recited in present claim 8 for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 7-9 are generic to a plurality of species.

The single species of condition is to be selected from:

(i) ischemia, (ii) epilepsy, (iii) hypoglycemia, (iv) Huntington's disease, (v) Alzheimer's disease, (vi) Parkinson's disease, (vii) amyotrophic lateral sclerosis (ALS), (viii) chronic pain, or (ix) nervous tissue trauma.

The species of conditions are independent or distinct because each are distinct from one another in etiology, pathophysiological manifestations, treatment protocol (i.e., duration of treatment, dosage amounts of pharmaceutical agents to be administered, frequency of treatment, etc.) and patient population such that a comprehensive search of the patent and non-patent literature for any one such disorder or condition would not necessarily result in a comprehensive search of any one or more of the other disorders or conditions recited in the present claims. Notwithstanding that Applicant may have established an underlying commonality to this genus of disorders or conditions, namely that each is associated with abnormal extracellular glutamate concentration in the brain or other nervous tissue, it remains that the art does not necessarily recognize such a shared characteristic as being common to each of the disparate disorders encompassed by the claim. For these reasons, they are, therefore, considered patentably distinct. It is noted that the discovery of the treatment of any one of the presently claimed disorders or conditions using the clavulanic acid presently claimed would not necessarily anticipate, reasonably suggest or render obvious the treatment of any one or more of the other disorders or conditions of the present claims for the same reasons described *supra*.

**Regarding the Election of Species Requirement:**

Applicant is advised that a proper reply to this requirement must include an identification of the **single** disclosed species of behavioral disorder if Applicant elects Invention I, providing page and line number identifying the written support for the elected species, **or** the identification of the **single** disclosed species of condition characterized by abnormal extracellular glutamate concentration in the brain or other nervous tissue if Applicant elects Invention III that is elected

consonant with this requirement and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon allowance of a generic claim, Applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 C.F.R. 1.141. If claims are added after the election, Applicant must indicate which are readable upon the elected species. Please reference MPEP §809.02(a).

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though this requirement be traversed (37 C.F.R. 1.143) and (ii) an identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should Applicant traverse on the ground that the inventions or species are not patentably distinct, Applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the Examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

The Examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of

the allowable product claim will be rejoined in accordance with the provisions of MPEP §821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 C.F.R. 1.116; amendments submitted after allowance are governed by 37 C.F.R. 1.312.

I n the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 C.F.R. 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. §103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicants are advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder.

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the Examiner withdraws the restriction requirement before the patent issues. See MPEP §804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie A. Royds whose telephone number is (571)-272-6096. The examiner can normally be reached on Monday-Friday (9:00 AM-5:30 PM).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on (571)-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Leslie A. Royds
Patent Examiner
Art Unit 1614

August 31, 2006

Ardin H. Marschel 9/16/06
ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER